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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,500	06/04/2001	John E. Ware	QMET-201	5112
24972	7590	08/03/2007		
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER LE, LINH GIANG	
			ART UNIT 3626	PAPER NUMBER
			MAIL DATE 08/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/873,500

Applicant(s)

WARE ET AL.

Examiner

Michelle Linh-Giang Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10, 12-15, 17-23, 25-27 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 12-15, 17-23, 25-27, 29-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### *Notice to Applicant*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 March 2007 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 8-23, 25-27, and 29-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), in view of Lewis (5,059,127).

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4. As per claim 1, Ware teaches a method of assessing the health status or health care of a patient, comprising the steps of:  
generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains (Ware; pg. 11, col. 2-3; pg. 12, cols 1-3);  
administering said test by providing one question at a time to said patient; and  
after each question (Ware; pg. 12, Col.1);  
evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (Ware; pg. 11, col. 3, par. 2; pg. 12 Col.1-2; pg. 13 Col. 1-2;)

Ware does not expressly teach:

varying a threshold as a function of said estimated score; and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside a said threshold.

However, these features are well known in the art as evidenced by Lewis. IN particular, Lewis teaches both random and adaptive testlet selection are well known in the art (Lewis; Col. 6, "Random vs. Optimum Selection"). Lewis teaches that the method of assigning variable threshold variables to particular testlests. It would have been obvious to add these features to the teachings of Ware with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

5. As per claim 2, Ware teaches further comprising the step of generating a report regarding the health status of said patient (Ware; pg. 12, col. 3, par.2).

6. As per claim 3, Ware teaches wherein said domain is a condition experienced or perceived by said patient (Ware; pg. 12, Col. 3, para. 1-2).

7. As per claim 4, Ware teaches wherein the step of dynamically modifying includes the step of ranking said plurality of questions in accordance with said estimated score; and selecting a question from said plurality of questions based on said ranking that has not been administered to said patient (Ware; pg. 12, col. 1).

8. As per claim 5, Ware teaches wherein the step of selecting comprises selecting a highest rank question (Ware; pg. 12, col. 1).

9. As per claim 6, Ware teaches wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold (Ware; pg. 12, col. 1, para. 2-3).

10. As per claim 8, Ware does not expressly teach wherein the step of generating selects said questions for said domain from a database having questions and answers pertaining to a plurality of domains.

However this feature is well known in the art as evidenced by Lewis. In particular, Lewis teaches that a mastery testing procedure called the "Item Response Theory" (IRT) was well known in the art (Lewis; Col. 1, line 63 to Col. 10, line 7). The IRT guides the selection of questions or items for inclusion in an examination. Furthermore, the IRT is used to determine the number of test items answered correctly or incorrectly (Lewis; Col. 3, lines 25-55). It would have been obvious to add these features to the Ware teachings with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

11. As per claim 9, Ware teaches wherein the step of administering includes the step of providing a list of possible answers for each question to said patient (Ware; Col. Pg. 13, Col.1-2).

12. As per claim 10, Ware teaches wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for errors or consistency (Ware; pg. 13, Col. 1-2).

13. As per claim 12, Ware does not expressly teach wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for estimating non-responsive answers to said test.

However this feature is well known in the art as evidenced by Lewis. In particular, Lewis teaches that a mastery testing procedure called the "Item Response

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Theory" (IRT) was well known in the art (Lewis; Col. 1, line 63 to Col. 10, line 7). The IRT guides the selection of questions or items for inclusion in an examination.

Furthermore, the IRT is used to determine the number of test items answered correctly or incorrectly (Lewis; Col. 3, lines 25-55). It would have been obvious to add these features to the Ware teachings with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

14. As per claim 13, Ware teaches wherein the step of reporting includes the step of comparing said answers provided by said patient with answers provided by other patients in said domain (Ware; Pg. 12, Col. 1-2 and Pg. 13, Col.1-2).

15. As per claim 14, Ware teaches administering includes the step of administering said test to said patients over a network, wherein said network is one of the following: an Internet, an intranet, a telephone network, and a wireless network (Ware; Pg. 12, Col. 3, par. 1-2).

16. As per claim 15, Ware teaches wherein the step of generating reports includes the step of generating said report over a network (Ware; Pg. 12, Col. 3, par. 1-2).

17. As per claim 17, Ware teaches wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, effectiveness of a treatment, physical health, emotional health, impact

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of asthma, job satisfaction, opinion polling, personality test, customer satisfaction and general overall health (Ware; pg. 12, Col. 1-3; pg. 13, col. 1-2).

18. Claims 18-23, 26-28, and 31-34 repeat the limitations of claims 1-6, 9-10, and 14-15 and 17 and the reasons for rejection are incorporated herein.

19. Claim 25 repeats the limitations of claim 8 and the reasons for rejection are incorporated herein.

20. Claim 30 repeats the limitations of claim 13 and the reasons for rejection are incorporated herein.

21. Claims 35-40 repeat the limitations of claims 1, 6, 17, and 18 and the reasons for rejection are incorporated herein.

22. As per claim 41, Ware does not expressly teach wherein at least two domains are selected to be assessed.

However, these features are well known in the art as evidenced by Lewis. IN particular, Lewis teaches both random and adaptive testlet selection are well known in the art (Lewis; Col. 6, "Random vs. Optimum Selection"). Lewis teaches that the method of assigning variable threshold variables to particular testlets. It would have been obvious to add these features to the teachings of Ware with the motivation of



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balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

23. Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), in view of Bair (6,067,523).

24. As per claims 42-45, Bair discloses:

(a) administering the test before a variable is introduced, wherein said variable includes a pharmaceutical such as Zoloft or Xanax, interventions or therapies (Fig. 1, 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14);

(b) readministering the questionnaire after the variable is introduced (Fig. 1, 16, 29-31, 27B, col. 6 lines 11-21, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51); and

25. (c) comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy (see "patient satisfaction and assessing treatment in order to gauge the effect of the treatment upon the behavioral problem) or impact of the introduction of said variable on said health status or health care of said patient (Abstract; Fig. 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51).

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The motivation for including the features of Bair within the method and system of Ware being to assess treatment and patient satisfaction (Bair; col. 15 lines 20-30).

### ***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Braun teaches a computer-based simulation examination of architectural practice (6,056,556).

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Linh-Giang Le whose telephone number is 571-272-8207. The examiner can normally be reached on 8 AM - 5PM, M-F.

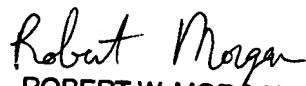
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-3600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



LLe

  
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